REMARKS/ARGUMENTS

Claims 1-3, 6, 7, 10, 11, 14, 15, 18, 19, 22 and 23 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication No. 2003/0039650 (U.S. '650).

According to the Examiner, U.S. '650 teaches a method to treat autoimmune diseases by exposing cells to an activating agent and reintroducing the cells into a patient. The immune cells can be PBMCs and may also be CD4+ and CD8+. According to the Examiner, the activating agents in U.S. '650 are anti-CD2, anti-CD3 and TGF-β. Since U.S. '650 teaches the use of IL-2, Claims 4, 5, 8, 9, 12, 13, 16, 17, 20 and 21 are objected to but otherwise allowable because they claim the use of IL-2.

To be anticipatory, a reference must disclose each and every limitation of the claims.

The broadest pending claims call for treating peripheral blood mononuclear cells with a regulatory composition comprising anti-CD2 and anti-CD3 and reintroducing the regulatory T cells to the patient to suppress an aberrant immune response. Because U.S. '650 does not disclose the use of an anti-CD2 in combination with anti-CD3, this reference is not anticipatory and the rejection should be withdrawn.

U.S. '650 is directed primarily to the making of compositions containing regulatory immune cells that have been made without the use of IL-2. As stated in U.S. '650 at paragraph 55:

> As used herein, activating proteins are molecules that when contacted with a T-cell population cause the cells to proliferate. T-cells generally require two signals to proliferate. Activating proteins thus encompasses the combination of proteins that provide the requisite signals, which include an initial priming signal and a second co-stimulatory signal. The first signal requires a single agent, such as anti-CD3 mAb, anti-CD2 mAb, anti-TCR mAb, PHA, PMA, and other such signals. The second signal requires one or more agents, such as anti-CD28, anti-CD40L, cytokines and other such signals. (Emphasis added.)

With regard to the Examiner's reliance on paragraph 98 of U.S. '650, it should be noted that this paragraph states:

> The cells can be activated either non-specifically with chemical agents such as PHA and PMA or with monoclonal antibodies such as anti-CD3 or anti-CD2. (Emphasis added.)

Since U.S. '605 does not teach the combination of anti-CD2 with anti-CD3, as set forth in the rejected claims, it is submitted that this reference does not anticipate the rejected claims.

Based on the foregoing, it is submitted that the claims are patentable over the art of record and a notice of allowance should be issued in connection with this application.

Respectfully submitted,
DORSEY & WHITNEY LLP

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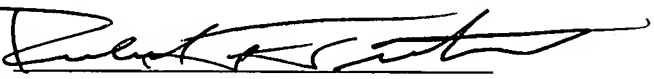
BY: 
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